



UNITED STATES PATENT AND TRADEMARK OFFICE

clw
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/708,693

11/07/2000

Se-Jin Lee

JHU 1120-15

2065

28213

7590

07/21/2006

DLA PIPER RUDNICK GRAY CARY US, LLP
4365 EXECUTIVE DRIVE
SUITE 1100
SAN DIEGO, CA 92121-2133

EXAMINER

ALLEN, MARIANNE P

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 07/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/708,693

Applicant(s)

LEE ET AL.

Examiner

Marianne P. Allen

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,9-11,15,19,22,26-29,31-33,37 and 39-43 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1, 9-11, 15, 19, 22, 26-29, 31-33, 37, 39-43 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's arguments filed 5/10/06 have been fully considered.

Claims 1, 9-11, 15, 19, 22, 26-29, 31-33, 37, 39-43 are pending and under consideration.

Claims 42-43 have been newly introduced.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

Applicant is again requested to update the status of the co-pending applications referenced in the specification.

Claim Objections

Claims 1, 19, 22, 33, 37, and 42-43 are objected to because of the following informalities: Claims 1, 19, and 33 are missing the closing parenthesis following “(SEQ ID NO: 4” and “(SEQ ID NO: 18.” Claims 22 and 37 recite “from the group consisting of as set forth in SEQ ID NO: 2.” This appears to be a word processing error and appears that “as set forth in” was intended to be deleted. It also appears that “is” may have been omitted. It appears that the claim should read “polypeptide is selected from the group.” Similarly, claims 42-43 appear to be missing a verb. Appropriate correction is required.

Double Patenting

Claims 1, 9-11, 15, 19, 22, 27-29, 31-33, 37, and 39-43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-11 of U.S. Patent No. 5,827,733. Although the conflicting claims are not identical, they are not patentably

Art Unit: 1647

distinct from each other because both sets of claims are directed to overlapping embodiments of murine and human GDF-8 polynucleotides, vectors, and host cells.

While the response submitted 5/10/06 refers to submission of a terminal disclaimer, no terminal disclaimer appears to have been submitted.

Claims 19, 22, 27-29, and 32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,500,664. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to overlapping embodiments of murine and human GDF-8 polynucleotides, vectors, and host cells.

While the response submitted 5/10/06 refers to submission of a terminal disclaimer, no terminal disclaimer appears to have been submitted.

Claims 1, 9-11, 19, 26, 32-33, and 39-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,465,239. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to overlapping embodiments of piscine GDF-8 polynucleotides, vectors, and host cells.

While the response submitted 5/10/06 refers to submission of a terminal disclaimer, no terminal disclaimer appears to have been submitted.

Claims 1, 9-11, 15, 19, 22, 27-29, 31- 33, 37, and 39-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-30 of copending Application No. 10/997,809. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the co-pending application is directed to polynucleotides encoding GDF-8 proteins from chickens corresponding to instant SEQ ID NO: 8 as well as vectors and host cells.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant is requested to identify all related co-pending applications with claims directed to polynucleotides, vectors, and host cells corresponding to or substantially similar to those in the present claims. Applicant is reminded that they must maintain a clear line of demarcation between applications.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 9-11, 15, 19, 22, 27-29, 31-33, 37, 39-40, and 42-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Barker et al. (U.S. Patent No. 6,369,201 B1).

Particular embodiments embraced by claim 1 are substantially purified peptides consisting of about amino acids 1-20 of SEQ ID NOS: 2, 4, 6, 8, 10, 12, 14, 16, 18, or 20 (the promyostatin signal peptide domain). These claims require signal peptide activity. These concepts are not disclosed by parent application 09/124,180.

Particular embodiments embraced by claims 33 and 37 are substantially purified peptides consisting of amino acids 20-262 of SEQ ID NOS: 2, 8, 10, 12, 14, 16, 18, or 20 or consisting of about amino acids 20-263 of SEQ ID NOS: 4 or 6 (the promyostatin prodomain). These claims require myostatin binding activity. These concepts are not disclosed by parent application 09/124,180.

Particular embodiments embraced by claims 19, 22, and 42-43 are substantially purified peptides consisting of about amino acids 268-375 of SEQ ID NOS: 4 or 6 or consisting of amino acids 267-374 of SEQ ID NOS: 2, 8, 10, 12, 14, 16, 18, or 20, (the promyostatin myostatin domain). These claims require muscle growth inhibitory activity. These concepts are not disclosed by parent application 09/124,180.

The amino acid residue ranges set forth in claims 26 and 41 are not disclosed in parent application 09/124,180. It is further noted that the zebrafish and salmon sequences are not provided by this parent application.

As such, benefit to the filing date of parent application 09/124,180 is denied for all claims. The effective filing date for these claims is considered to be 27 July 2000.

Barker et al. is valid prior art against the instant claims as this application was filed on 18 February 1999.

Art Unit: 1647

Barker et al. discloses the full length sequences for human, murine, rat, chicken, baboon, bovine, porcine, ovine, turkey, and zebrafish promyostatin polypeptides. Barker's SEQ ID NOS: 29, 27, 28, and 30 corresponding directly to instant SEQ ID NOS: 4, 6, 2, and 10, respectively. Barker's SEQ ID NOS: 31-34 and 36 have a conservative substitution in a single position with respect to instant SEQ ID NOS: 12, 14, 16, 8, and 20, respectively. Barker's SEQ ID NO: 35 has two mismatches to instant SEQ ID NO: 18. Particular fragments of these polypeptides are also disclosed. See at least Figure 1A-1D and column 3, lines 25-45. Note that none of the mismatches occurs in the promyostatin myostatin domain and only one mismatch (for SEQ ID NO: 18) occurs in the promyostatin signal peptide domain. However, as the mismatch in SEQ ID NO: 18 is at amino acid three, this is considered to be within the claim limitation of "about 1-20." Polynucleotides encoding the proteins, expression vectors, and isolated host cells are disclosed.

This disclosure anticipates the instant claims as the claims all use "comprising" or open language and include the full length sequences as well as the fragments disclosed by Barker et al.

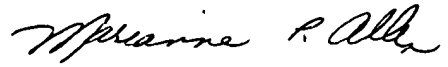
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1647

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Marianne P. Allen
Primary Examiner
Art Unit 1647

7/17/06

mpa